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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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HAHN LOESER & PARKS, LLP  
TWIN OAKS ESTATE  
1225 W. MARKET STREET  
AKRON, OH 44313

EXAMINER

RAIZEN, DEBORAH A

ART UNIT PAPER NUMBER

2873

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/894,351

Applicant(s)

LEGERTON ET AL.

Examiner

Deborah A. Raizen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-28 and 45-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,4-24,45 and 46 is/are allowed.
- 6) ☒ Claim(s) 25,27 and 47-50 is/are rejected.
- 7) ☒ Claim(s) 26 and 28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Priority***

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in China on 20 October 2000 (application number 00129863.1). It is noted, however, that applicant has not filed a certified copy of the Chinese application as required by 35 U.S.C. 119(b).

### ***Drawings***

2. The drawings were received on July 26, 2004. These drawings are accepted.

### ***Claim Objections***

3. Claim 49 is objected to because of the following informalities: in line 1, the words "least" and "one" are misspelled in the phrase "at leas on". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 47 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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6. The limitation “independently” in line 9 of claim 47, which refers to the design of the connecting zone, contradicts the limitations in lines 12 and 13, “matched to the slope of the central zone” and “matched to the slope of the at least one peripheral zone.”
7. Claim 48 is indefinite because it depends on claim 47 and inherits the contradiction.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Siviglia (4,787,732, of record)
10. In regard to claim 25, Siviglia discloses (Fig. 3) a contact lens comprising: a central zone (20) having a posterior surface with a curvature (col. 4, lines 16-18); a connecting zone (the elbow region between central zone 20 and peripheral zone 22) having a posterior surface (Fig. 3) provided adjacent and concentric to said central zone (Fig. 2, where the zone is located at the line between zones 20 and 22, and Fig. 3), and at least one peripheral zone (22) having a posterior surface provided adjacent and concentric to said connecting zone (Figs. 2 and 3), said peripheral zone being integral with said connecting zone (Fig. 3) and being formed as a truncated conoid over at least a substantial portion thereof (Fig. 3 and col. 5, lines 18-23), wherein the lens is designed to impart desired forces to said cornea to alter the shape of the cornea in a predetermined manner (col. 7, lines 16-20 and col. 1, lines 38-42).

In regard to claim 27, in the Siviglia contact lens, the parameters of connecting zone depth (the short axial length of the elbow region) and peripheral zone angle (the angle of the conical surface, or conoid, with the optical axis) are derived by methods (col. 7, lines 46-66) that yield the same product as the recited methods.

11. Claim 47, as understood, is rejected under 35 U.S.C. 102(b) as being anticipated by Woodford (4,297,008, of record). Woodford discloses a corneal contact lens (70 in Fig. 4b) comprising a central zone (optical zone, col. 4, lines 16-17) having a posterior surface curvature (Fig. 4b), a connecting zone (the aspheric curve beginning at the periphery of the optical zone and continuing to a flatter portion, col. 4, lines 16-18) having a posterior surface (Fig. 4b) and provided adjacent to said central zone (Fig. 4b and col. 4, lines 51-55: it is generated by rotation of tool 60), said connecting zone having a shape defined as a sigmoidal curve (working surface 66 of tool 60 has an S-shape: col. 4, lines 64-68; also, Figs. 4a-4f), and at least one peripheral zone (the flatter portion of the aspheric curve near the edge of the lens, corresponding to the bevel labeled 16 in Fig. 1, in which only the posterior surface is beveled) having a posterior surface (Fig. 4b) and provided adjacent to said connecting zone (Fig. 4b),

wherein the central zone and the at least one peripheral zone are designed independently from one another (col. 4, lines 56-63; col. 5, lines 36-38) such that each of the central and at least one peripheral zone have a width positioned relative to a predetermined portion of the cornea on which the lens is placed (col. 5, lines 11-26, and Figs. 4c-4f: use of different conic section shapes for generating the working tool surface allows each of the central and peripheral zones to have a

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different width; the table in col. 5 lists those widths, except that the values listed include the width of the connecting zone; as disclosed in col. 5, lines 36-43, the fitter determines the optical zone diameter, which determines the width of the central zone positioned relative to the central portion of the cornea, and the fitter determines the lens diameter, which determines the width of the peripheral zone positioned relative to the peripheral portion of the cornea), and the connecting zone being independently designed to connect to the central zone at the periphery of the central zone, and to the at least one peripheral zone at the periphery of the connecting zone (as the term “independently” is understood, the lens designer can independently choose various shapes and sizes of the two conic sections used to generate the work tool, after the widths of the optical, or central, zone and the lens diameter are determined), with the connecting zone being shaped such that the portion adjacent the central zone is matched to the slope of the central zone and the portion adjacent the peripheral zone is matched to the slope of the at least one peripheral zone (Fig. 4b shows that at the inner and outer ends of the connecting zone, the slopes match the slopes of the central and peripheral zones).

12. Claims 47-50 are rejected under 35 U.S.C. 102(b) as being anticipated by El Hage (5,695,509, of record).

In regard to claim 47, as understood, El Hage discloses a corneal contact lens (Fig. 5B) comprising a central zone (labeled 10, and extending to within about 1 mm in the figure from the point labeled 12, including regions having different radii of curvature) having a posterior surface curvature (the curvature of the bottom side of the lens in Fig. 5B in the central zone, which includes regions having different radii of curvature), a connecting zone (the region between the

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points 12 and 14 and, additionally, 1 mm in the figure on each side of those points) having a posterior surface (the bottom side of the lens in Fig. 5B in the connecting zone) and provided adjacent to said central zone (Fig. 5B), said connecting zone having a shape defined as a sigmoidal curve (Fig. 5B), and at least one peripheral zone (labeled 16, and extending to within about 1 mm in the figure from the point labeled 14) having a posterior surface (the bottom side of the lens in Fig. 5B in the connecting zone) and provided adjacent to said connecting zone (Fig. 5B),

wherein the central zone and the at least one peripheral zone are designed independently from one another (col. 7, lines 40-45 and col. 8, lines 1-6) such that each of the central and at least one peripheral zone have a width positioned relative to a predetermined portion of the cornea on which the lens is placed (col. 8, lines 7-17; the central zone, which includes the region labeled in El Hage “central pressure zone” and a portion of the region labeled “relief zone”, has a width that is larger than the central diameter  $cd$ ), and the connecting zone being independently designed to connect to the central zone at the periphery of the central zone, and to the at least one peripheral zone at the periphery of the connecting zone (because the limitation “independently designed” contradicts the limitation below that the slopes are matched, this limitation cannot be considered; a similar limitation might be given weight if it recited which particular parameters of the connecting zones are chosen independently of which particular parameters of the other zones), with the connecting zone being shaped such that the portion adjacent the central zone is matched to the slope of the central zone and the portion adjacent the peripheral zone is matched to the slope of the at least one peripheral zone (Fig. 5B: if the central zone extends to within 1 mm in the figure from the point labeled 12, the slope is the same before and after the partition

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between a central zone and a connecting zone; the slope is also the same before and after the current partition between the connecting and peripheral zones).

In regard to claim 48, the El Hage corneal contact lens is designed to impart desired forces to said cornea to alter the shape of the cornea in a predetermined manner (col. 1, lines 52-60).

In regard to claim 49, El Hage discloses a corneal contact lens (Fig. 5B) comprising a central zone (labeled 10, and extending to within about 1 mm in the figure from the point labeled 12, including regions of different curvatures) having a first width (about 35 mm in the figure, corresponding to about 60% of the total diameter of the lens, disclosed to be 10 mm in col. 8, lines 10-11, or 6 mm in the actual lens), at least one peripheral zone (labeled 16, and extending to within about 1 mm in the figure from the point labeled 14) having a second width (6 mm in the figure, or 1 mm in the actual lens), and a connecting zone (the region between the points 12 and 14 and, additionally, 1 mm in the figure on each side of those points) positioned between the central zone and at least one peripheral zone (Fig. 5B) and having a shape defined as a sigmoidal curve (Fig. 5B), the connecting zone having a third width (5.5 mm in the figure, or 0.95 mm in the actual lens), wherein the first and second widths are greater than the third width (6 mm and 1 mm are greater than 0.95 mm).

In regard to claim 50, the El Hage corneal contact lens is designed to impart desired forces to said cornea to alter the shape of the cornea in a predetermined manner (col. 1, lines 52-60).



*Allowable Subject Matter*

13. Claims 26 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

See paper no. 5, mailed August 26, 2003, for a statement of reasons for the indication of allowable subject matter.

14. Claims 1, 2, 4-24, 45, and 46 are allowed.

The following is an examiner's statement of reasons for allowance: The prior art taken either singularly or in combination fails to anticipate or fairly suggest the limitations of claims 1, 2, 4-24, 45, and 46, in such a manner that a rejection under 35 U.S.C. 102 or 103 would be proper.

The prior art fails to teach a combination of all the features in claim 1. For example, these features include the detailed structure recited and the functional limitations that require underlying structural features not found in the prior art, especially the functional limitation that the sigmoidal curve of the connecting zone is spaced from the cornea substantially over its extent to create a void space thereunder when the lens is positioned on the cornea of a patient, in combination with all the other limitations of the claim. The terms "substantially", "over its extent", and "void space" overcome the rejection based on El Hage because the El Hage lens is spaced from the cornea by only 29  $\mu\text{m}$  at its anchor zone 14, which is included in the sigmoidal curve of the connecting zone (Fig. 7 and col. 10, lines 12-18 of El Hage), and because the El

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Hage lens does not have a void space under the sigmoidal curve over the extent of the sigmoidal curve.

Claims 2, 4-6, 9-12, 15-22, 24, 45, and 46 depend on claim 1 and are therefore allowed as well.

For claims 7, 8, 13, 14, and 23, see the examiner's statement of reasons for allowance in paper no. 5, mailed August 26, 2003.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Response to Arguments***

15. Applicants' arguments filed December 29, 2003, with regard to claims 25 and 27 as amended December 29, 2003, have been fully considered but they are not persuasive.

Applicants argue that the prior art of Siviglia in no way relates to reshaping the cornea.

However, the passages cited above show that the Siviglia lens does maintain a constant radius of curvature of the cornea, which would otherwise vary from hour to hour.

16. Applicants' arguments filed July 26, 2004, with respect to the rejection of claims 1-28 and 45-51 under 35 U.S.C. §112, first paragraph, have been fully considered and are persuasive. The rejection of claims 1, 2, 4-28 and 45-50 under 35 U.S.C. §112, first paragraph, has been withdrawn.

17. Applicants' Remarks of July 26, 2004, suggest that claim 51 is still pending. However, claim 51 is not included in the listing of claims submitted July 26, 2004. It has therefore not

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been considered in the current action. It will be considered to be a new claim if listed in Applicants' next Amendment and will need a new number.

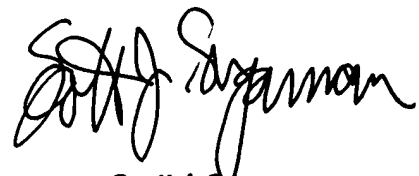
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A. Raizen, Ph.D., J.D., whose telephone number is (571) 272-2336. The examiner can normally be reached on Monday-Friday, from 10:00 a.m. to 3:00 p.m. Eastern Standard Time (a part-time schedule).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Georgia Y. Epps can be reached at (571) 272-2328. The USPTO central official fax number is (703) 872-9306 (please note that this number is different from the previous two numbers provided until the summer of 2003).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. For information about the PAIR system, see <http://pair-direct.uspto.gov> or <http://www.uspto.gov/ebc/index.html>, or contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free) or at 703-305-3028 or at 703-308-6845 between the hours of 6 a.m. and midnight Monday through Friday EST, or by e-mail at: [ebc@uspto.gov](mailto:ebc@uspto.gov).

dar

  
Scott J. Sugarman  
Primary Examiner